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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,923	12/24/2003	Lynn T. Antonelli	82828	8392

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EXAMINER

TOTH, KAREN E

ART UNIT PAPER NUMBER

3736

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,923	ANTONELLI ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,11-13 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 3,10,14, 20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/24/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruth'211 (US Patent 4746211).

Ruth'211 discloses an apparatus for measuring a physiological event occurring in a human body (column 2, lines 21-23). Said apparatus comprises a laser source (element 15) that is directed upon a surface (element 5) (column 4, lines 44-45); said surface moves in relation to the physiological event (column 4, lines 52-54). Said apparatus further comprises a detector (element 30) that captures the reflected laser beam (column 4, line 59). The velocity of surface movement (element v_s) is captured via the intensity of the reflected signal (column 2, lines 44-46).

Regarding Claim 2, Ruth'211 further discloses that said apparatus also comprises a processing circuit (see Figure 2), including a time-dependent integrator (element 24) that is used to analyze the captured velocity signal with respect to time (column 9, lines 11-24).

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Regarding Claim 5, Ruth'211 further discloses that said apparatus also comprises a display device (element 29) that is used to display the physiological measurement (column 9, line 24). Said measurements are in the shape of waveforms, plotted with respect to time (Figures 5-6).

3. Claims 11, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruth'211.

Ruth'211 discloses a method of measuring a physiological event comprising directing a laser beam to a skin surface (column 4, lines 44-45); reflecting and scattering the light off the surface, and capturing said reflected light (column 4, lines 45-46 and 59); determining the intensity of the reflected light signal, which is a result of the movement of the surface, and using said intensity to determine the velocity of surface movement (column 2, lines 24-39).

Regarding Claim 15, Ruth'211 further discloses that the light is scattered over the skin surface of the subject, and that the speckle pattern movement is determined by the skin's velocity (column 3, lines 47-51).

Regarding Claim 16, Ruth'211 further discloses that a display (element 29) is used to display the measured velocity values (column 9, lines 21-24; see also figures 5-6).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

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be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Khair'729 (US Patent 6533729).

Ruth'211 discloses all the elements of the current invention, as applied to Claim 1 above, except for the laser source and detector being contained in a single housing.

Khair'729 teaches an optical blood pressure measurement apparatus wherein the laser source (element 30) and detectors (element 17) are contained within a single housing (element 12) (Figures 1-4) to reduce the amount of space needed to operate the apparatus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have housed the laser source and detector of the apparatus of Ruth'211 in a single housing, as taught by Khair'729, in order to reduce the amount of space needed to operate the apparatus.

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6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Khair'729.

Ruth'211 discloses all the elements of the current invention, as applied to Claim 11 above, except for the physiological event in question being blood pressure.

Khair'729 teaches a non-invasive method for measuring blood pressure comprising using a light source (element 30) to deflect light off a subject and capturing it with a detector (element 17) (column 6, lines 25-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the apparatus of Ruth'211 to measure blood pressure, as taught by Khair'729, because that measurement is a well-known physical parameter useful for patient analysis.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Gorti'658 (US Patent 5954658).

Ruth'211 discloses all the elements of the current invention, as applied to Claim 5 above, except for the physiological event in question being respiration.

Gorti'658 teaches an apparatus for measuring physiological events that comprises a laser source (element 1) that directs a laser beam at a subject's surface (element 4), and a detector for capturing the reflection of the laser beam from the subject (element 5) (column 5, lines 30-45, and Figure 1). Gorti'658 teaches that said apparatus may be used to measure respiration rate (column 3, line 65, to column 4, line 1), because respiration rate is a commonly measured physiological parameter that is used to monitor a subject's condition.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the physiological event measuring apparatus of Ruth'211 to measure respiration rate, as taught by Gorti'658, to monitor the subject's physiological condition.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Gorti'658.

Ruth'211 discloses all the elements of the current invention, as applied to Claim 11 above, except for the physiological event in question being respiration.

Gorti'658 teaches using a physiological event measuring apparatus comprising a laser source (element 1) that directs a laser beam at a subject's surface (element 4), and a detector for capturing the reflection of the laser beam from the subject (element 5) (column 5, lines 30-45, and Figure 1) to measure physiological event parameters, such as respiration rate (column 3, line 65, to column 4, line 1), because respiration rate is a commonly measured physiological parameter that is used to monitor a subject's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the physiological event measuring method of Ruth'211 to measure the respiratory rate of a subject, as taught by Gorti'658, because it allows monitoring of the subject's condition.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Amano'850 (US Patent Application Publication 2004/0147850).

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Ruth'211 discloses all the elements of the current invention, as applied to claim 5 above, except for the physiological event being blood pressure and the waveform containing dicrotic notch information.

Amano'850 teaches an apparatus for measuring blood pressure comprising a light source (element 64) that emits light, which is then deflected off the subject and captured by a detector (element 65) (paragraph [0094]). Said apparatus is used to capture the pulse wave of the subject (paragraph [0097]), and said pulse waveform (element MH) is used to capture dicrotic notch (element P4) information (paragraphs [0101-0102]), which is used to calculate various physical parameters relating to heart function (paragraphs [0061, 0063, 0064]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have captured dicrotic notch information from a subject as taught by Amano'850 when using the physiological event measuring apparatus of Ruth'211 in order to measure cardiac function parameters.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Amano'850.

Regarding Claim 8, Ruth'211 in view of Amano'850 discloses all the elements of the current invention, as applied to claim 6 above, except for the processor being capable of analyzing the blood pressure to determine systolic time interval parameters.

Amano'850 further teaches that the measured pulse values and dicrotic notch data are used to calculate the estimated systolic time, which is then used

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to calculate other parameters (paragraph [0063]) in order to more fully analyze the patient's cardiac cycle.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the measured pulse values and dicrotic notch data of the apparatus of Ruth'211 to determine systolic parameters, as taught by Amano'850, in order to more fully analyze the patient's cardiac cycle.

Regarding Claim 9, Ruth'211 in view of Amano'850 discloses all the elements of the current invention, as applied to claim 6 above, except for the processor being capable of analyzing the blood pressure to determine heart rate.

Amano'850 further teaches that the patient's heart rate is calculated from once cycle of the measured heartbeat output (paragraph [0031]), since this is a commonly measured and monitored physical parameter.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have calculated the heart rate of a patient using the apparatus of Ruth'211, as taught by Amano'850, since that is a commonly measured and monitored physical parameter.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Amano'850.

Ruth'211 discloses all the elements of the current invention, as applied to Claim 15 above, except for the physiological event in question being a blood pressure, and wherein the method includes producing a blood pressure waveform representation by plotting skin surface velocity with respect to time that also contains dicrotic notch information.

Ruth'211 further discloses that measured values are displayed on a display device (column 9, lines 21-24; see also figures 5-6).

Amano'850 teaches a method for measuring physiological parameters comprising using a light source (element 64) to deflect light off a subject and capturing it with a detector (element 65) (paragraph [0094]). The physiological parameter measured by the detector is the pulse wave of the subject, which is used to find the dicrotic notch of the waveform (paragraph [0063]) in order to calculate various physical parameters relating to heart function (paragraphs [0061, 0063, 0064]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Ruth'211 to measure and display the pulse wave of a subject, as suggested by Amano'850, and further displaying information related to the dicrotic notch of the subject's waveform in order to calculate cardiac function parameters.

12. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth'211 in view of Amano'850

Regarding Claim 18, Ruth'211 in view of Amano'850 discloses all the elements of the current invention, as applied to Claim 17 above, except for the method further comprising analyzing the blood pressure waveform to determine systolic time interval parameters.

Amano'850 further discloses using the measured pulse waveform and dicrotic notch data to determine the patient's systolic parameters (paragraph [0063]), in order to more fully analyze the patient's cardiac cycle.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the pulse waveform and dicrotic notch data from the apparatus of Ruth'211 to determine systolic parameters of the patient, as taught by Amano'250, in order to more fully analyze the patient's cardiac cycle.

Regarding Claim 19, Ruth'211 in view of Amano'850 discloses all the elements of the current invention, as applied to Claim 17 above, except for the method further comprising analyzing the blood pressure waveform parameters to determine heart rate.

Amano'850 further teaches using measured blood pressure ejection data to determine the heart rate of the patient (paragraph [0031]), since this is a commonly measured and monitored physical parameter.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of calculating the patient's heart rate in the method of Ruth'211, as taught by Amano'850, since this is a commonly measured and monitored physical parameter.

Allowable Subject Matter

13. Claims 3, 10, 14, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5363855 to Drzwiecki, disclosing a noninvasive pressure waveform monitor.

US Patent 5949546 to Lee, disclosing an interference apparatus.

US Patent Application Publication 2003/0191400 to Shalman, disclosing a system for determining values of hemodynamic parameters.

US Patent 5778878 to Kellam, which discloses laser Doppler microscopy methods.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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